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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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|-----------------|-------------|----------------------|---------------------|------------------|

10/813,214

03/29/2004

Lasse Wesseltoft Mogensen

8465/43

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7590

07/23/2007

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EXAMINER

MACNEILL, ELIZABETH

ART UNIT

PAPER NUMBER

3767

MAIL DATE

DELIVERY MODE

07/23/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/813,214

Applicant(s)

MOGENSEN ET AL.

Examiner

Elizabeth R. MacNeill

Art Unit

3767

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 July 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 50-96 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 60-64 is/are allowed.
- 6) ☒ Claim(s) 50-59 and 65-96 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>4/2/07; 7/2/07</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 50-57, 59, 65-68, 72-85, 89, and 93-96 are rejected under 35 U.S.C. 103(a) as being unpatentable over Funderbunk et al (US 6,093,172) in view of Turner et al (US 4,817,603).

Funderbunk teaches an injector assembly comprising a sterile insertion set with a housing (20), tubing (22) and a hollow cannula (26), a device housing (28), a plunger (30), with flexible plastics members (56) with insertion needle (12) and support structure (144), and a spring (36) with a trigger (138) and lock (78). Funderbunk does not disclose a cover over the forward end of the housing.

Turner discloses a spring loaded needle with a plunger and housing (Fig 1) where the forward end of the housing is covered with a removable cap (14) which is sealed to the housing prior to use.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to include a sealing cap on the device of Funderbunk in order to prevent the insertion needle or cannula from being contaminated prior to use.

Regarding claims 53,79 Funderbunk discloses inserting a glucose sensor (Col 1 line 27)

Art Unit: 3767

3. Claims 50-59, 65-88, and 90-92 are rejected under 35 U.S.C. 103(a) as being unpatentable over Funderbunk et al (US 6,093,172) in view of Karakashian (US 3,937,219)

Funderbunk teaches an injector assembly comprising a sterile insertion set with a housing (20), tubing (22) and a hollow cannula (26), a device housing (28), a plunger (30), with flexible plastics members (56) with insertion needle (12) and support structure (144), and a spring (36) with a trigger (138) and lock (78). Funderbunk does not disclose a cover over the forward end of the housing.

Karakashian discloses an injection assembly (4) sealed with a sterile cover (1) which has a membrane and allows for flow-through sterilization (Fig 1).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to include a sterile cover on the device of Funderbunk in order to prevent the insertion needle or cannula from being contaminated prior to use.

Regarding claims 53,79 Funderbunk discloses inserting a glucose sensor (Col 1 line 27)

Regarding claim 58, it would have been obvious to one of ordinary skill in the art to include the shelf life of the assembly on the sterile packaging for safety purposes.

Allowable Subject Matter

4. Claims 60-64 are allowed.

5. The following is a statement of reasons for the indication of allowable subject matter: the prior art does not teach or suggest the use of a spring member comprising a number of individual, flexible plastics strips extending around a respective part of the periphery of the plunger, in combination with the other elements of the claims.

Response to Arguments

6. Applicant's arguments filed 2 July 2007 have been fully considered but they are not persuasive. Regarding the insertion set being placed within the injector device housing; applicant is referred to Fig 9 of Funderbunk. Additionally, applicant has not claimed that the entire insertion set must be within the housing, or that the wings 24 are even a part of the insertion set. Clearly, cannula 26 and housing 20 are within the injector device housing in Fig 9. The rejection is maintained.

Conclusion

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Art Unit: 3767

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth R. MacNeill whose telephone number is (571)-272-9970. The examiner can normally be reached on 9:00-5:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ERM

Elizabeth R. MacNeill
7/18/07

KEVIN C. SIRMONS
SUPERVISORY PATENT EXAMINER

Kevin C. Sirmons